AMENDED IN SENATE MAY 15, 2001

SENATE BILL No. 1169

Introduced by Senator Alpert

February 23, 2001

~~An act to add and repeal Section 1157.8 of the Evidence Code, and to add and repeal Part 5.5 (commencing with Section 128850) to Division 107 of the Health and Safety Code, relating to health.~~ *An act to amend Section 4052 of the Business and Professions Code, relating to pharmacy.*

LEGISLATIVE COUNSEL'S DIGEST

SB 1169, as amended, Alpert. ~~Patient safety data reporting and analysis~~ *Pharmacy.*

Under existing law, a pharmacist may not, in general, furnish a dangerous drug except upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian. However, existing law provides for certain exemptions.

This bill would authorize a pharmacist to initiate emergency contraception drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs.

~~Under existing law, the Office of Statewide Health Planning and Development is vested with responsibilities in the areas of health planning and data reporting.~~

~~This bill would require the office to contract with an organization recognized as operating a quality-oriented data base program to create a central reporting data base and to receive and analyze information relating to medical events involving the occurrence or near occurrence of compromises of patient safety or of the quality of health care delivery~~

~~by any health care professional, facility, or organization licensed by the state.~~

~~This bill would provide for the making of voluntary reports to this contractor, and for the analysis of reports by the contractor to attempt to determine safeguards to prevent future occurrences of the conduct reported. It would provide for summary quarterly reports to be made by the contractor to the office and the State Department of Health Services.~~

~~The bill would contain various safeguards for the identity of reporters and the subjects of reports.~~

~~The bill would provide for the repeal of its provisions on January 1, 2006.~~

Vote: majority. Appropriation: no. Fiscal committee: ~~yes~~ *no*. State-mandated local program: no.

The people of the State of California do enact as follows:

~~SECTION 1. This act shall be known, and may be cited, as the~~

SECTION 1. Section 4052 of the Business and Professions Code is amended to read:

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded medication to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(B) Ordering drug therapy-related laboratory tests.

(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(5) (A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):

(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(ii) Ordering drug therapy related laboratory tests.

(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(iv) Adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the patient's prescriber for the individual patient, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by Section 4073.

(B) A patient's prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the

appropriate participation of the pharmacist and the direct care registered nurse.

(ii) Require that the medical records of the patient be available to both the patient's prescriber and the pharmacist.

(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) Initiate emergency contraception drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs.

(b) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility. Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (1) successfully completed clinical residency training or (2) demonstrated clinical experience in direct patient care delivery.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

~~California Patient Safety Act.~~

~~SEC. 2. The Legislature finds and declares all of the following:~~

~~(a) It is important to identify deficiencies in, and opportunities for, improving health care patient safety systems, for the purpose of identifying and encouraging the adoption of structural safeguards.~~

~~(b) The establishment of a voluntary, confidential, anonymous nonregulatory system to accept reports of these deficiencies and opportunities will maximize the number of reports and best encourage a systems approach to error reduction.~~

~~(c) Human factors research strongly supports the creation of such a forum for analysis, education, and the improvement of health care quality and safety. The data collected under such a reporting system can be used to evaluate medical equipment and procedures and aid in the development and improvement of medical equipment, procedures, and systems to strengthen the foundation of health care patient safety.~~

~~(d) Effective reduction of unintended adverse patient outcomes in any health care organization or setting requires a reporting system in which patients, their families, and health care providers can report detailed descriptions of medical events related to safety or quality assurance without fear of regulatory or punitive consequences.~~

~~(e) To promote the confidence that the system will be used to improve patient safety systems, rather than to punish or regulate, the collection and analysis should be carried out by a single entity which does not have existing regulatory or oversight responsibilities.~~

~~(f) Although numerous administrative, civil, and criminal mechanisms exist for disciplining health care professionals and facilities who fail to meet the standard of care, these systems, by themselves, have failed to create optimal patient safety. Recent research into the issue indicates that these punitive systems will not suffice in improving patient safety and that voluntary reporting systems acknowledge the inevitability of human error and understand that errors occur because individual health care professionals cannot consistently outperform unsafe or potentially unsafe systems operating within health care delivery. Under these voluntary systems of reporting, medical event analysis is system or process oriented rather than focused on individual blame.~~

~~(g) This collecting entity will have responsibility for managing reports related to the data collected under this reporting system, and will create data base structures for the purpose of providing patient safety hazard alerts, distributing safety information, without identifying specific facilities or individuals, and effectively communicating aggregate information in the form of quarterly reports to the State Department of Health Services, the Office of Statewide Health Planning and Development, and the public.~~

~~(h) Data reported and collected pursuant to this reporting system will be provided with protection from subpoena, discovery, or use for other purposes, such as civil litigation, arbitration, or other administrative actions.~~

~~(i) To ensure continued attention to the effectiveness of this system, this reporting system will be eliminated on January 1, 2006, unless extended by the Legislature.~~

~~SEC. 3. Section 1157.8 is added to the Evidence Code, to read:~~

~~1157.8. (a) The identity of a medical event reporter, the reports made, and the data regarding medical events reported and collected, under Part 5.5 (commencing with Section 128850) of Division 107 of the Health and Safety Code, shall not be subject to subpoena, nor shall it be disclosed or compelled to be produced in any civil, administrative, or other noncriminal proceeding, or be deemed admissible as evidence in any civil, administrative, or other tribunal or court for any reason, with the exception of information upon which the report is based, and if and only if that information exists independent of the reporting process mandated by that part and is otherwise discoverable under any other provision of law. No person involved in the investigation, collection, review, development, or submission of the data under Part 5.5 (commencing with Section 128850) of Division 107 of the Health and Safety Code shall be subject to subpoena or compelled or allowed to testify regarding the data.~~

~~(b) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.~~

~~SEC. 4. Part 5.5 (commencing with Section 128850) is added to Division 107 of the Health and Safety Code, to read:~~

~~PART 5.5. PATIENT SAFETY DATA REPORTING AND ANALYSIS REQUIREMENTS~~

~~128850. The Office of Statewide Health Planning and Development shall contract with an organization recognized as operating a quality-oriented data base program, such as the Institute of Medical Quality, to create a central reporting data base and to receive and analyze information relating to medical events involving the occurrence or near occurrence of compromises of patient safety or of the quality of health care delivery by any health care professional, facility, or organization licensed by the state.~~

~~128851. For purposes of this part:~~

~~(a) ''Medical events involving the occurrence or near occurrence of compromises of patient safety or of the quality of health care delivery by any health care professional, facility, or organization licensed by the state'' means any occurrence that the reporter believes did result, or could have resulted, in a compromise of patient safety or of the quality of health care delivery.~~

~~(b) ''Reporter'' means any health care facility, health care professional, patient, or person who is involved in any manner in a medical event described in subdivision (a) and who reports the event to the contractor.~~

~~128852. The contractor provided for pursuant to Section 128850 shall develop a medical event reporting form for voluntary submission to the contractor. The report form shall include, but not be limited to, the date of the event and a summary of the event. The report form shall contain a tear-off portion that contains the information that identifies the person or entity submitting the report.~~

~~128853. Within 72 hours of receipt of a report, the contractor shall review the report, contact the medical event reporter, if necessary, to obtain additional information about the event for purposes of evaluating potential systems safeguards that would reduce the likelihood of the medical event reoccurring, detach that portion of the report which contains identifying information and return it to the reporting individual or entity by United States mail. The contractor shall delete any identifying information as to the person or entity submitting the report, or the health care professional or institution that is the subject of the report.~~

~~128854. On or before January 1, 2003, and quarterly thereafter, the contractor shall submit to the office and the State Department of Health Services and prepare for distribution to the public, a summary report regarding the information received and analyzed pursuant to the central reporting system, without any identifying information concerning the reporters or the subjects of the reports. This report shall include an analysis and interpretation of the data received by the contractor and recommendations for improvement of patient safety and quality of care related thereto.~~

~~128855. A reporter who reports pursuant to this chapter shall not be civilly or criminally liable for any report authorized by this part.~~

~~128856. A supervisor or administrator for any health care professional, facility, or organization shall not impede or inhibit the making of a report authorized by this part. A person making a report pursuant to this part shall not be subject to any sanction for making the report.~~

~~128857. It is the intent of the Legislature that the administrative cost incurred by the office in administering this part, including the cost incurred by the organization contracting with the office, be funded pursuant to the Budget Act.~~

~~128858. This part shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.~~

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